

d.) Remarks

Examiner has withdrawn claims 6-10, 12-19 and 25-28, claim 11 has been amended, and claims 31-32 have been added. Support for these amendments can be found throughout the specification (see pages 6 and 7). No new matter or new issues are believed presented. Therefore, claims 6-19 and 25-32 are pending.

Remarks Regarding Restriction Requirement

The Examiner has imposed a Restriction Requirement withdrawing claims 6-10, 12-19 and 25-28. Applicant respectfully traverses this requirement and incorporates all of the arguments made in the prior amendment filed November 19, 2004, and the prior restriction response filed February 23, 2004.

Remarks Regarding Alleged Double-Patenting

Claim 11 allegedly stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-25 of co-pending Application No. 10/053,871. Applicant respectfully traverses this rejection. An appropriate Terminal Disclaimer is attached hereto and this rejection is moot.

Remarks Regarding 35 U.S.C. § 103(a)

Claims 11 and 29-30 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Shih et al. (U.S. Patent No. 4,026,767) in view of Harlow and Lane. Applicant respectfully traverses this rejection.

Remarks Regarding Shih

The prior art method is necessarily not capable of taking less than two hours to perform since it expressly states lengthy procedure time is a problem for at least the following reasons: detection might be missed with cultures made over a shorter period of time, risk of contamination, and reliability (col. 1, lines 20-27) without teaching a solution. The two week period described in the prior art was stated to be a problem, and then a period which ranged from several hours to a few days and preferably over night was disclosed (col. 5, lines 1-3). Therefore,

it must be concluded that prior art not only taught against it, but was incapable of performing the procedure in less than two hours.

Remarks Regarding Harlow and Lane

Harlow and Lane disclose selecting the lowest level of antigen that will yield a strong signal (approximately 10,000-50,000 cpm) (Chapter 14; page 589) teaching away from detecting the claimed sensitivity. Moreover, nowhere in Harlow and Lane is the teaching of formazan. Therefore, it would not have been obvious to one of ordinary skill in the art to combine the teachings of Shih with Harlow and Lane to make the claimed invention.

Thus, the rejection of claims 11 and 29-30, under 35 U.S.C. § 103(a), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 112, first paragraph

Claims 11 and 29-30 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses this rejection. In the office action, the Examiner alleges that the specification only supports the detection of bacteria. Although applicant respectfully disagrees, in an effort to expedite prosecution, applicant has amended independent claim 11 to recite wherein the microorganisms are bacteria.

Thus, the rejection of claims 11 and 29-30, under 35 U.S.C. § 112, first paragraph, is moot.

Remarks Regarding MPEP § 2172.01

Claims 11, 29 and 30 stand rejected, under MPEP § 2172.01, as allegedly missing essential steps. Applicant respectfully traverses this rejection. However, in an effort to expedite prosecution, applicant has amended independent claim 11. In the office action, the Examiner alleges that detection of reporter molecule is not correlated. Although applicant respectfully

disagrees, claim 11 has been amended to recite detecting "reporter molecules that form reporter-primary antibody complexes".

Accordingly, the rejection of claims 11, 29 and 30, under MPEP § 2172.01, is moot and applicant respectfully requests that it be withdrawn.

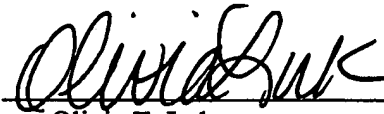
Conclusion

If there are any additional fees due with the filing of this Amendment, including any additional fees for a further extension of time, not herein accounted for, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 50-1682 referencing Attorney Docket No. 144517.00201.

Respectfully submitted,
Powell Goldstein LLP

Date: December 14, 2005

By



Olivia T. Luk

Registration No. 57,730

Enclosed: Terminal Disclaimer

Customer No. 51362

Powell Goldstein LLP
901 New York Avenue, NW.
Suite 300
Washington, DC 20001-4413
Telephone: (202) 347-0066
Facsimile: (202) 624-7222